



MEMORANDUM OF UNDERSTANDING

ON

**LIBBY AMPHIBOLE: THE LIBBY COMMUNITY BASED RESEARCH INITIATIVE
AND OTHER SUPERFUND HEALTH RESEARCH**

BETWEEN THE

U.S. ENVIRONMENTAL PROTECTION AGENCY

AND THE

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

I. PURPOSE/OBJECTIVES/GOALS

This Memorandum of Understanding (MOU) serves to set forth the authorities, responsibilities, and procedures under which the U.S. Environmental Protection Agency (EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR) are cooperating and coordinating on key Superfund environmental public health research including, but not limited to, the studies of the epidemiological aspects and assessment of human health impact of Libby Amphibole exposures. In FY 2007, EPA, with the assistance of ATSDR, identified and recovered \$13.0 million of unexpended "no year" Superfund appropriations that, in accordance with the terms of EPA's prior year appropriation acts, EPA transferred to ATSDR to carry out activities authorized by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA and ATSDR have since agreed that EPA will return the \$13.0 million to ATSDR to conduct and accelerate high priority environmental public health research to provide information that will allow the public health community to better understand and manage the adverse health effects associated with exposure to Libby Amphibole asbestos, as well as enhance both agencies' overall performance in addressing CERCLA goals and objectives.

Deleted: 6

Deleted: 6

II. BACKGROUND

Since 1999, the ATSDR has worked in collaboration with the EPA and a number of other partners in evaluating the public health consequences of community exposures to amphibole asbestos and other similar fibers from Libby, Montana. Vermiculite that contains amphibole asbestos was

Deleted: May 23

Deleted: - EPA OCFO comments are included

June 2, 2008 DRAFT,

DRAFT - DELIBERATIVE

mined in Libby and also shipped to over two hundred sites all over the United States. Inhalational exposures occurred among workers, their family members and residents of Libby and in other impacted communities as a result of mining, processing or other handling and use of the contaminated ore and related products and waste materials.

The ATSDR has documented a significant number of asbestos-related deaths and health effects related to the Libby Asbestos Superfund site and other locations where the contaminated ore was shipped around the United States for processing. Some of ATSDR's past activities include conducting environmental exposure evaluations, health statistics reviews, community screenings, and disease-specific surveillance. While these activities have been very supportive to EPA's Superfund response efforts to date, significant additional epidemiologic and human health studies are necessary to determine the toxicity of the Libby Amphibole and to assist EPA and ATSDR with quantification of protective future exposure levels for both cancer and non-cancer health effects. ATSDR's May 2003 Public Health Assessment recommended more research, specifically: toxicological investigation of the risks associated with low-level exposure to asbestos, especially Libby asbestos, clinical research on treatments for mesothelioma and asbestosis, and epidemiology studies to better characterize the link between exposure to asbestos and disease.

Deleted: "safe"

EPA's pre-FY 2001 fiscal year appropriation acts required that EPA transfer appropriated Superfund resources to ATSDR to enable ATSDR to carry out its responsibilities under CERCLA. These funds were "no year" appropriations available until expended. On March 23, 2007, the Office of Management and Budget (OMB) issued Memorandum No. M-07-12, "Guidance to OMB Bulletin No. 06-03, *Audit Requirements for Federal Financial Statements*, on Auditing Allocation Transfers," to Federal agencies clarifying financial reporting responsibilities for transferring, or "allocating," budget authority from one entity to another within or to another Federal department (i.e., parent/child reporting) under OMB Bulletin No. 06-03, *Audit Requirements for Federal Financial Statements*, and OMB Circular A-136, *Financial Reporting Requirements*. The department (i.e., parent) that transfers budget authority to another Federal entity (i.e., child) must report the child agency's (e.g., ATSDR) budgetary and proprietary information in its financial statements, whether material to the parent (e.g., EPA) or not. To satisfy the revised requirements of OMB Circular No. A-136, EPA requested the current status of budgetary and proprietary activity relating to each allocation transfer interagency agreement (IAG) ATSDR had received from EPA. In September 2007, EPA received from ATSDR \$13.0 million in unexpended Superfund appropriations that EPA had transferred to ATSDR in prior years. EPA and ATSDR have since agreed that EPA will return the \$13.0 million to ATSDR and these funds will be used in a timely manner to address the categories of research needs specified in Exhibit I of this MOU. While the focus of this MOU is the research related to the Libby Amphibole, these resources may also be used to address other critical CERCLA health issues.

Deleted: 6

Deleted: 6

III. AUTHORITIES

A. ATSDR. The Administrator of ATSDR has authority to carry out this MOU and expend the \$13.0 million in funds EPA will transfer under Section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986; 42 U.S.C. Section 9604(i) and the terms of EPA pre-FY 2001 appropriation acts.

Deleted: 6

Deleted: May 23

Deleted: - EPA OCFO comments are included

June 2, 2008 DRAFT

DRAFT - DELIBERATIVE

B. U.S. Environmental Protection Agency: The Administrator of EPA has statutory authority to cooperate and coordinate with ATSDR under Section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986; 42 U.S.C. Section 9604(i).

C. ATSDR and EPA are subject to OMB Circular No. A-136, *Financial Reporting Requirements*; OMB Bulletin No. 06-03, *Audit Requirements for Federal Financial Statements* (August 23, 2006); and, OMB Memorandum No. M-07-12, Guidance to OMB Bulletin No. 06-03, *Audit Requirements for Federal Financial Statements*, on Auditing Allocation Transfers (March 23, 2007).

IV. ROLES AND RESPONSIBILITIES

A. EPA and ATSDR will endeavor to collaborate on implementation of the ATSDR Work Plan for Libby Amphibole: Libby Community Based Research presented in Exhibit 1.

B. EPA and ATSDR will endeavor to identify and implement additional CERCLA health studies. ATSDR and EPA will strive to work collaboratively and to reach consensus on the objectives of specific studies.

Deleted: ATSDR and EPA will coordinate to ensure that each study addresses critical CERCLA health issues.

C. EPA and ATSDR will collaborate on developing and implementing a public communication program for the work conducted under this MOU.

D. While the funds are "no year" under the terms of the Superfund appropriation language and are available until expended, ATSDR agrees that it will obligate the funds by September 30, 2013 and expend the funds by September 30, 2015 or return the balance to EPA so that the funds may be credited to the Superfund Trust Fund under 31 USC 1555. EPA may waive this requirement on the basis of adequate justification from ATSDR.

Deleted: c

Deleted: expend

E. Since ATSDR has other appropriated funds to cover fixed administrative and overhead costs and overhead charges have been previously incurred during the original transfers, ATSDR shall endeavor to minimize use of these funds for administrative and overhead purposes.

F. As provided for in OMB Circular No. A-136, *Financial Reporting Requirements*, and OMB Memorandum No. M-07-12, Guidance to OMB Bulletin No. 06-03, *Audit Requirements for Federal Financial Statements*, on Auditing Allocation Transfers (March 23, 2007) ATSDR, as the receiving department (i.e., child agency), must not report any information relating to the transfer appropriation account on its own financial statements. ATSDR will provide its budgetary and proprietary information to the EPA (i.e., parent agency) to be reported in the EPA's financial statements. ATSDR shall submit to EPA its budgetary and proprietary information by means of a full United States Standard General Ledger (USSGL) trial balance no later than 12 calendar days following the end of the reporting period or a date required by EPA to meet its reporting and auditing deadlines, whichever comes first. The trial balance should be emailed to EPA's Reports and Analysis Staff, Office of Financial Management (see contact information below). The two agencies will coordinate to ensure that the EPA auditor's needs, as they relate to the allocation

Deleted: May 23

Deleted: - EPA OCFO comments are included

June 2, 2008 DRAFT,

DRAFT - DELIBERATIVE

transfer, are met. ATSDR will continue to execute quarterly Federal Agencies' Centralized Trial-Balance System (FACTS II) submission to the U.S. Department of Treasury.

G. ATSDR will provide quarterly progress reports with a status of ATSDR-lead activities being performed pursuant to this MOU and the activities/timelines in Exhibit 1. The quarterly progress reports should also include a utilization status of the funds that are transferred. Quarterly progress reports should be submitted to the U.S. EPA Superfund program contact person listed below.

H. For all reporting purposes, including utilization, ATSDR will segregate the funds identified in Exhibit 1 for the LCBRI from the remaining transferred funds available for use at ATSDR's discretion.

V. LIMITATIONS

A. All commitments made in this MOU are subject to the availability of allocation transfer funds and other appropriated funds. Nothing in this MOU, in and of itself, obligates ATSDR or EPA to enter into any contract, assistance agreement, interagency agreement, or other financial obligation.

B. This MOU applies only to ATSDR and EPA and does not create rights in third parties.

VI. POINTS OF CONTACT

The following individuals are designated points of contact for the MOU:

U.S. Environmental Protection Agency:

Superfund Program Contact Information:

Barnes Johnson

Deputy Director, Office of Superfund Remediation and Technology Innovation

1200 Pennsylvania Ave, N.W.

MC 5201P

Washington, DC 20460

703-603-8960 (phone)

703-603-9146 (fax)

Quarterly Financial Statements Reporting Contact Information:

Eva N. Abeles, General Ledger Lead Accountant,

(202) 564-1865 (phone)

abeles.eva@epa.gov (email)

Karen Kirkwood, Financial Statements Lead Accountant,

(202) 564-1189 (phone)

kirkwood.karen@epa.gov (email)

Reports and Analysis Staff, Office of Financial Management

June 2, 2008 DRAFT

Deleted: May 23

Deleted: - EPA OCFO comments are included

DRAFT - DELIBERATIVE

Office of the Chief Financial Officer
1200 Pennsylvania Ave, N.W.
MC 2733R
Washington, DC 20460
(202) 564-2586 (fax)

Agency for Toxic Substances And Disease Registry

G. David Williamson, PhD
Director, Division of Health Studies
4770 Buford Highway, NE, MS-F-61
Atlanta, GA 30341
770-488-0705 (phone)
770-488-3385 (fax)

Please provide ATSDR's point of contact information for financial information.

Comment [E1]: Please ensure
ATSDR provides this information.

VII. MODIFICATION/DURATION/TERMINATION

This MOU will be effective when signed by all parties and shall remain in effect until September 30, 2013. This MOU may be amended at any time by the mutual written consent of the parties. This MOU may be terminated by either party at anytime by one party notifying the other party in writing 90 days in advance of the termination date. All obligations pursuant to OMB Circular No. A-136 and OMB Bulletin No. 06-03 may not be terminated.

VIII. APPROVAL

Agency for Toxic Substances And Disease Registry

(Signature Block)

Date

Howard Frumkin, M.D., M.P.H., Dr.P.H.

Director, National Center for Environmental Health/Agency for Toxic Substances and Disease
Registry, Centers for Disease Control and Prevention

U.S. Environmental Protection Agency

(Signature Block)

Date

Susan Parker Bodine, Esq.

Assistant Administrator, Office of Solid Waste and Emergency Response

Deleted: May 23

Deleted: - EPA OCFO comments are
included

| June 2, 2008 DRAFT.

DRAFT - DELIBERATIVE

EXHIBIT 1

ATSDR Work Plan for Libby Amphibole: The Libby Community Based Research Initiative (LCBRI)

Introduction and Purpose

Since 1999, the Agency for Toxic Substances and Disease Registry (ATSDR) has worked in collaboration with the United States Environmental Protection Agency (EPA) and a number of other partners in evaluating the public health consequences of community exposures to amphibole asbestos and other similar fibers from Libby, Montana. Vermiculite that contains amphibole asbestos was mined in Libby and also shipped to over two hundred sites all over the United States. Inhalational exposures occurred among workers, their family members and residents of Libby and in other impacted communities as a result of mining, processing or other handling and use of the contaminated ore and related products and waste materials. The health effects of exposure to asbestos have been well documented previously in occupational and environmental settings. The purpose of this document is to provide the framework for an ATSDR funded Libby Community Based Research Initiative (LCBRI) and other related work. This work will be conducted in close collaboration with EPA and a number of other potential partners and will focus on the epidemiological aspects and assessment of human health impact of these exposures to further address the research and public health needs related to Libby Amphibole exposures. In the planning and implementation of this work, ATSDR will focus and prioritize those activities that directly support and complement EPA's Libby Toxicity Assessment Action Plan (LTAAP)¹. These plans together outline EPA's and ATSDR's ongoing commitment to provide information that will allow the public health community to better understand and manage the adverse health effects associated with exposure to Libby Amphibole asbestos.

Broader Implications for Public Health

Despite a developing body of scientific knowledge and a significant asbestos related knowledge base, ATSDR and EPA have identified a number of relevant and significant science and data gaps related to these exposures. Addressing these gaps is important to enable scientists, clinicians and policy makers to better prevent and/or manage past, current and future exposures to Libby Amphibole.

In addition, the knowledge gained may have significant impact on understanding of similar exposures in other settings such as occupational exposures to similar fibers and non-commercial

¹ In January 2007, EPA convened a group of more than 30 scientists from EPA, the Agency for Toxic Substances and Disease Registry and the National Toxicology Program to identify data gaps and recommend additional studies to support the baseline human health risk assessment for the Libby, Montana Asbestos site. These recommended studies became the "Libby Toxicity Assessment Action Plan." The Plan is comprehensive program of 12 interrelated project areas designed to ensure that the Superfund program has information it needs to support future needs such as a baseline risk assessment for the Libby Site or future five-year reviews and to improve the understanding of the long-term public health effects associated with exposure to Libby amphibole asbestos.

June 2, 2008 DRAFT

Deleted: May 23

Deleted: -- EPA OCFO comments are included

DRAFT - DELIBERATIVE

asbestos exposures in communities and their related health risks. Regardless of the mechanisms, studies of former workers and residents of Libby have shown that people who were exposed to Libby Amphibole-contaminated vermiculite have an increased likelihood of developing asbestos-related health effects, including asbestosis, lung cancer, mesothelioma, and pleural disease.

ATSDR Guiding Principles for Future Research and Public Health Activities

In its Libby related research, ATSDR has utilized several important “guiding principles” for prioritizing projects and allocating resources. In the past, projects that fulfill one or more of these criteria have been considered favorably by the Agency and these will continue to provide guidance and future direction for the Agency.

These principles for future work include the following:

- Protective of public health
- Advance the relevant body of scientific knowledge
- Assist ATSDR and partners in public health decision making and policy-making (e.g. EPA risk assessment)
- Provide information essential for preventing or mitigating exposures
- Serve the needs and concerns of the affected community

ATSDR Priority Focus Areas for Libby Amphibole

Based on assessment of the existing body of knowledge and related science gaps for Libby Amphibole related research, ATSDR will complete ongoing work and support future work designed to provide a better understanding of the epidemiology of Libby Amphibole related health outcomes. ATSDR proposes to focus its future efforts on specific projects designed to further clarify and address specific knowledge gaps related to the nature and severity of health outcomes, exposure and related health risks.

- **Key specific areas of activity which ATSDR will manage include:**
 - **Epidemiological studies of persons exposed to Libby asbestos:**
 - Health assessment of persons originally exposed to Libby Amphibole in childhood.
 - Expanded epidemiological evaluation of persons exposed in Libby, including those with low level environmental exposures. The studies will consider the evaluation of susceptible populations, the potential use of biomarkers, and the clinical course of disease. Activities may include additional follow-up medical screening, improved exposure questionnaires and use of additional clinical data (e.g. CT scanning, complete pulmonary function test results).
 - Assessment of non-pulmonary health effects of Libby Amphibole exposure (e.g. auto-immune conditions).

Deleted: May 23

Deleted: – EPA OCFO comments are included

June 2, 2008 DRAFT,

DRAFT - DELIBERATIVE

- Surveillance of Libby Amphibole related health outcomes including development of data systems and local infrastructure to link various existing and available data sets with NIOSH and EPA.
- Further epidemiologic investigation of the **Marysville, Ohio** cohort; newly obtained worker exposure data may be useful in the development of reference toxicity values (worker study published previously).
- **Dosimetric modeling** and simulation for pulmonary deposition and clearance of fibers. In the future, a valid dosimetry model would allow quantitative prediction of internal dose across species to facilitate improved understanding of the exposure-response relationship in humans.
- Limited update of the **Tremolite Asbestos Registry (TAR)** including review of mortality and cancer incidence.
- Study of **digital vs. plain film chest radiographs** for B reading (currently underway in collaboration with NIOSH).

Additional information on cost estimates and timelines is provided in Table 1.

Mechanisms and Respondent Requirements

ATSDR anticipates utilizing a combination of funding mechanisms to conduct the work with a major portion of new work being conducted under a cooperative agreement. Summary of key requirements for the cooperative agreement respondents include:

- Academic institutions with significant experience and expertise in clinical and public health aspects of asbestos exposure and disease including Libby Amphibole
- Substantial “track record” of development and implementation of community based public health research programs with history of relevant publication in peer reviewed literature
- Experience, resources and infrastructure for working closely with the community, state, local and Federal partners and stakeholders in development of a “research and public health agenda”
- Commitment to maintain a long term presence in the Libby community to enhance communication with and between stakeholders, provide management of data and related infrastructure issues and facilitate community based research activities

ATSDR expects that the recipient will establish and operate a “field station” in Libby. The office will be staffed by qualified researchers and support staff as appropriate to conduct and/or coordinate the proposed activities. Close, ongoing collaboration and communication with internal partners at the parent institution and with the community, ATSDR, EPA and other external partners is anticipated and expected. The recipient will provide leadership and support for convening and maintaining a scientific advisory committee for the research effort and a community advisory group to represent the needs of the Libby community. These initiatives must incorporate and/or link with existing efforts for research oversight and community involvement.

ATSDR expects that the research initiative will build upon work already underway in Libby or related to other sites that received Libby vermiculite. Therefore the grantee must also develop

June 2, 2008 DRAFT.

Deleted: May 23

Deleted: – EPA OCFO comments are included

DRAFT - DELIBERATIVE

mechanisms for continuation of "work in progress" with existing partners.

Summary

Since 1999, ATSDR has been involved in understanding and addressing the public health consequences of exposure to contaminated vermiculite ore from Libby, Montana. This document provides a proposed work plan for ATSDR's ongoing and future efforts and the implementation of a Libby Community Based Research Initiative in support of and complementing EPA's LTAAP activities. In conducting additional future work, ATSDR will continue to build upon its existing expertise in epidemiology, environmental public health and community based research and will seek to build and enhance relationships with key stakeholders and partners to forge an effective public health research agenda for Libby Amphibole.

Table 1 (Estimated Project Funding and Timelines for LCBRI)

Activity Description	Estimated Time Line	Estimated Cost 1 st Year	Estimated Total Cost (\$)	Lead Agency/Comments
Epidemiology studies -Childhood exposure -Expanded epi studies -Non-pulmonary health effects	2-5 years	1,000,000	4,000,000	Recipient TBD
- Ongoing surveillance and data systems	5 years	165,000	825,000	Appropriate local provider ¹
Marysville Epidemiology	2 years	500,000	1,000,000	TBD
Dosimetric modeling	2 years	150,000	275,000	EPA
Limited update of TAR	2 years	250,000	500,000	ATSDR/State of Montana
B-Reader Study	1 year	200,000	200,000	ATSDR/NIOSH- in progress
Intramural costs (ATSDR)	5 years	180,000	1,200,000	ATSDR
GRAND TOTAL		2,445,000	8,000,000	

Comment [E2]: Edits on footnote 1 below reflect our assumption that the amounts reflected here exclude the congressional earmark.

Deleted: ²

¹ Excludes a separate FY 2008 congressional earmark of approximately \$250,000 provided to the Libby Center for Asbestos Related Diseases (CARD) for similar activities.

Deleted: ² Of the \$13 million being returned to ATSDR, the activities outlined in Exhibit 1 are estimated to cost \$8 million. ATSDR has discretion as to how the remaining \$5 million will be utilized consistent with CERCLA Section 104(i) and pre-FY 2001 appropriation acts.

Deleted: May 23

Deleted: - EPA OCFO comments are included

June 2, 2008 DRAFT,